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Treatment with Opioids Is Not Associated with Poor Outcomes Among Older Adults with Lumbar Spinal Stenosis Receiving Epidural Injections

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Abstract

Study Design: Secondary analysis of a randomized controlled trial

Objective: To assess how baseline treatment with opioids is associated with pain and function in older adults with lumbar spinal stenosis who receive epidural injections.

Summary of Background Data: Data were obtained from the Lumbar Epidural Steroid injections for Spinal Stenosis (LESS) trial, a double-blind, multisite, randomized controlled trial.

Methods: Baseline treatment with opioids was assessed from electronic medical record prescription pharmacy data or from health utilization records collected from patients. We calculated adjusted changes in back pain numerical rating scale (NRS), leg pain NRS, and back-related disability (Roland Morris Disability Questionnaire (RMDQ) scores) from baseline to 3 weeks and to 6 weeks among patients treated and not treated with opioids at baseline using generalized linear regression.

Results: Baseline treatment with opioids was not significantly associated with back pain intensity (adjusted difference in means at 3 weeks of follow-up between patients treated with

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Potential Conflicts of Interest:

None

opioids at baseline versus not (\pm 95% confidence interval) 0.1 (–0.7, 0.7)), leg pain intensity (–0.2 (–0.9, 0.4)), or back-related function (–0.8 (–2.1, 0.4)). We found similar results at 6-weeks of follow-up.

Conclusion: Among older adults with lumbar spinal stenosis who are receiving epidural injections, those treated with opioids at baseline had similar outcomes to those who were not.

Keywords

Lumbar spinal stenosis; epidural steroid injections; injections; injection; opioid; pain; interventional spine; lumbar spine

Introduction:

Symptomatic lumbar spinal stenosis (LSS) is a clinical syndrome caused by narrowing of the lumbar spinal canal.¹ Although LSS is a leading reason for spinal surgery in older adults,² nonsurgical treatments are also commonly used. These include analgesic medications, exercise, physical therapy and/or epidural glucocorticoid injections.³ Opioids are commonly prescribed for pain in those with LSS,³ despite limited evidence of their effectiveness for use in non-malignant musculoskeletal pain⁴ and the known risks of misuse, adverse effects and fatal overdoses.⁵ Some longitudinal studies of patients with low back pain have found associations between opioid prescriptions and subsequent greater pain intensity and functional limitations,⁶ and associations with greater risk of long-term disability.⁷ If opioid prescriptions not only predict but influence poor outcomes in patients with low back pain or lumbar spinal disorders, this is of considerable interest since the decision to prescribe opioids is potentially modifiable.

While substantial research has characterized opioid prescriptions among younger and middle-aged adults with low back pain, less work has focused on older adults, and fewer studies have examined *specific* spine syndromes associated with low back pain, such as LSS. The Lumbar Epidural Steroid injections for Spinal Stenosis (LESS) trial was a double-blind, multisite, randomized controlled trial (RCT) of 400 patients which evaluated the effectiveness of epidural glucocorticoid injections for lumbar spinal stenosis symptoms and neurogenic claudication.^{8,9} We conducted a secondary analysis of the LESS RCT to examine how treatment with opioids was associated with pain and function outcomes among patients with LSS who received epidural injections and how these injections may have affected subsequent opioid treatments. Our aim was to determine whether baseline treatment with opioids predicted pain and functional outcomes among patients with LSS regardless of whether they received a lumbar epidural injection with or without corticosteroids, after adjusting for potential confounding factors. We hypothesized that patients who were treated with opioids at baseline would have worse pain and function outcomes, as has been previously described among different patient populations.^{7,10–12} As crossover to the alternative treatment not originally received (glucocorticoid-lidocaine or lidocaine-alone) was allowed at 6 weeks post-randomization and could be considered an important outcome of the initial treatment, we also sought to determine if baseline treatment with opioids affected crossover rates regardless of whether patients initially received glucocorticoid-lidocaine or lidocaine-alone injections.

3. Methods:

We conducted secondary analyses of data from the LESS RCT which took place from 2011 through 2014 and included patients with lumbar central spinal stenosis and moderate-to-severe leg pain and disability who were randomized to receive epidural injections of either glucocorticoids-lidocaine or lidocaine-alone. The trial methods are described in detail elsewhere⁸ and are briefly summarized here.

Participants and Procedures

The LESS trial was conducted at 16 sites in the United States. Patients with symptomatic LSS who were referred for epidural glucocorticoid injections, were at least 50 years of age and had evidence of central lumbar spinal stenosis on magnetic resonance imaging or computed tomography were considered for participation in the study. Additional criteria included an average pain rating of greater than 4 on a 0–10 scale for pain in the lower back, buttock, leg, or a combination of these sites on standing, walking or spinal extension in the past week; worse pain in the buttock, leg, or both compared to the back; and a score of 7 or higher on the 0–24 Roland-Morris Disability Questionnaire¹³ (RMDQ). Patients were excluded if they had spondylolisthesis requiring surgery, had a history of lumbar surgery, or had received epidural glucocorticoid injections in the last 6 months.

Patients were randomized to receive standard epidural injections of glucocorticoids-lidocaine or injections of lidocaine-alone. They had the option to repeat the injection at 3 weeks if they wished and to cross over to the other treatment group after the 6-week assessment. Electronically-concealed permuted-block randomized assignments were performed for each recruitment site and blinding of patients and providers was maintained throughout the treatment and follow-up periods.

Expert physicians trained to administer the injections were instructed to choose the injection level one spinal level below the maximal canal stenosis for interlaminar injections. For transforaminal injections, the root level was chosen based on where symptoms were most pronounced. Bilateral and multilevel transforaminal injections were allowed. The glucocorticoid was chosen based on the physician's usual practice. The glucocorticoid injectable solution consisted of 1–3ml of lidocaine followed by 1–3ml of either triamcinolone, dexamethasone, betamethasone, or methylprednisolone. The lidocaine-alone injection procedure was identical to that for the glucocorticoid–lidocaine injection except that the injectable solution was an equivalent volume of lidocaine-alone.

Measures

The co-primary outcomes of the initial LESS trial were the RMDQ score and average buttock, hip, or leg pain intensity in the previous week as rated on a numerical rating scale (NRS) at 6 weeks. Multiple secondary outcomes were also measured.⁸

Baseline demographic (age, gender, race, marriage status, employment status, and education level) and clinical (duration of pain, expected pain levels in 3 months as measured by the Pain Expectation Scale, RMDQ, back pain intensity as measured by a NRS,¹⁴ leg pain intensity (NRS), Patient Health Questionnaire depression 8-item scale¹⁵

(PHQ-8), Generalized Anxiety Disorder 7-item scale¹⁶ (GAD-7), Fear Avoidance Beliefs Questionnaire¹⁷ (FABQ), Pain Catastrophizing Scale¹⁸ (PCS), and health-related quality of life¹⁹ (EQ-5D-VAS)) data were collected.

Baseline treatment with opioids, reflecting reported opioid use or fills prior to randomization, which occurred on the day of the epidural injection, was measured through two different methods, depending on the electronic medical record (EMR) data availability at each study site. In the first method (“EMR ascertainment”), used at study sites where EMR data was available for all written and filled prescriptions, data on opioid prescriptions filled prior to the epidural injections were collected passively through the EMR (n=205 patients; 55% of the study sample). For these patients, we defined baseline treatment with opioids as having a filled prescription for any opioid that would have extended into the period 31 days prior to randomization. Daily Morphine Equivalent Doses (MEDs) were calculated by converting each patient’s total daily opioid dose into morphine equivalents and then averaging this value over the 31 days prior to randomization. The second method (“health utilization record ascertainment”) was used at study sites where comprehensive EMR data were not available (n=166; 45% of our study sample). At these sites, opioid data prior to randomization were collected from “health utilization records” collected by research staff. The health utilization records asked patients to record the names, doses, and number of pills consumed per day of prescription opioid medications that they had taken in the past month. Daily MEDs were calculated by converting each patient’s total daily opioid dose into morphine equivalents and then averaging this value over the 31 days prior to randomization. We considered patients with indications of opioid prescription fills in the EMR or who reported taking opioids in the health utilization record as “treated with opioids”.

Statistical Analysis

For descriptive purposes, we summarized sociodemographic and clinical characteristics of participants with and without baseline treatment with opioids, stratified by glucocorticoids-lidocaine or lidocaine-alone treatment assignment. We determined statistical significance using chi-square tests for categorical variables and t-tests for continuous variables, with two-sided p-values <0.05 considered statistically significant. We compared the baseline to 3-week changes in back pain NRS, leg pain NRS, and disability (RMDQ scores) among patients with and without treatment with opioids at baseline using generalized linear regression. We report crude means and 95% confidence intervals (95% CIs), as well as means and 95% CIs adjusted for whether patient had EMR ascertainment/health utilization record ascertainment to determine baseline opioid data, whether the patient was randomized to receive glucocorticoid-lidocaine or lidocaine-alone, age, gender, race (white vs not white), whether the patient had a partner, patient employment (full/part time vs. other), patient education, duration of pain, patient expectations of pain relief at baseline, and baseline RMDQ, back pain NRS, leg pain NRS, PHQ-8, GAD-7, FABQ, PCS, and EQ-5D-VAS. Adjustment variables were chosen based on conceptual importance. The primary analysis and focus of interpretation was the multivariable-adjusted results, which we expected to be less affected by confounding. We also calculated the adjusted difference in means between patients who were treated with opioids at baseline and those who were not using generalized linear regression. We used the same methods to examine outcomes at 6 weeks, 6 months,

and 12-months. We also compared the rates of crossover at 6 weeks in the groups with versus without opioid treatment at baseline using logistic regression to estimate odds ratios (ORs) and 95% CIs, adjusting for the same variables listed above. Crossover was defined as a patient request at 6 weeks to have the alternative treatment other than their randomized injection. Although the initial LESS trial had 400 participants, we excluded 29 (7.3%) participants from the current analyses due to missing baseline patient-reported outcome and/or demographic data. Due to the low frequency of missing data, a complete-case analysis was conducted. SAS version 9.4 (Cary, North Carolina) was used for all analyses.

4. Results:

Table 1 shows characteristics of participants at baseline, stratified by whether patients were treated with opioids at baseline and by randomized group. The analysis included 371 patients at baseline who were randomized into the glucocorticoid-lidocaine (N=191) and the lidocaine-alone (N=180) arms. Among all participants, 77 (20.8%) were treated with opioids at baseline, including 37 (patients in the lidocaine-alone arm and 40 patients in the glucocorticoid-lidocaine arm. Mean (\pm standard deviation) MEDs among those taking opioids were low (25.5 ± 58.6). In both treatment arms, a greater proportion of those treated with opioids at baseline were non-white, not married/living with a partner, and had less education. Those treated with opioids had slightly worse average baseline RMDQ scores and also had worse PHQ-8 depression, GAD-7 anxiety, catastrophizing (PCS) scores, and self-rated health (EQ-5D-VAS) scores (Table 1). Baseline back and leg-pain NRS scores among patients who were being treated with opioids at baseline were similar to the scores of those who were not.

After adjusting for baseline covariates and randomized treatment, patients treated with opioids at baseline did not differ significantly from those not treated with opioids in improvement at 3 and 6 weeks in back pain intensity, leg pain intensity, or RMDQ scores (Table 2). At 6-month follow-up, we found that patients who were not treated with opioids at baseline had statistically significantly lower back pain (1.1 NRS points [95% CI 0.4, 1.7]) and leg pain NRS scores (0.8 NRS points [95% CI 0.1, 1.5]) compared to patients who were treated with opioids. However, by the 12-month follow-up there was no statistically significant difference in back pain (0.3 NRS points [95% CI -0.4, 1.0]) and leg pain NRS scores (0.6 NRS points [95% CI -0.2, 1.3]) between patients who were treated with vs. without opioids. The difference between the significance of results at the 6- and 12-month follow-up did not appear to be due to sample size, as there was only a trivial decrease in sample size of only 7 or 8 patients between the 6- and 12-month time points for the back pain and leg pain outcomes, respectively. There were no significant differences in RMDQ scores between those who were and were not treated with at either 6 months or 12 months.

Among patients who were treated with opioids at baseline, 23 (29.9%) crossed over compared to 119 (40.5%) patients who did not, but the adjusted odds of crossover were not statistically significant between the two groups (OR: 0.59, 95% CI: 0.33, 1.07).

5. Discussion:

The overall goal of these analyses of data from the LESS RCT was to better understand how opioid medications were associated with pain and function outcomes among patients with LSS who received epidural injections. Our study found no overall pattern of statistically significant differences in improvement in back pain, leg pain, functional limitations, or rates of cross-over to the epidural injection treatment not originally received between 3-week and 12-month follow-up, when comparing patients who were treated with opioids at baseline and those who were not.

Many studies examining associations between treatment with opioids and poor pain outcomes are cross-sectional, and do not allow assessment of temporal sequences (i.e., what preceded what).^{12,20} Some prior longitudinal studies have found that patients with low back pain treated with opioids have worse subsequent outcomes compared to patients who were not.^{7,10,11} However, treatment with opioids is strongly associated with concurrent higher levels of pain, disability, and psychological distress (e.g., depression, anxiety), and these factors themselves are predictive of poor outcomes.^{20–25} In the current study, we also found that patients treated with opioids at baseline had lower quality of life and greater levels of disability, depression, anxiety, and catastrophizing. In order to reduce confounding, studies examining the association between baseline treatment with opioids and back-related outcomes must account for these opioid-related baseline factors; prior studies may not have adequately addressed this confounding.^{18–20} Studies using administrative databases or health records have little ability to adjust for potential confounders, as validated measures of psychological factors and disability are usually not available.⁷ In the current study, we adjusted for a wide range of potential confounders using validated measures and found no overall pattern of associations between baseline treatment with opioids and subsequent functional outcomes. These findings echo those from an earlier study of 1954 older adults with low back pain conducted by our group, in which unadjusted analyses found significantly worse subsequent disability outcomes in those who filled prescriptions for opioids at baseline, but no differences were found once adjusting for potential confounders.²⁴ Taken together, the findings from these two studies suggest that while treatment with opioids may be associated with worse *concurrent* levels of comorbidities and disability among older patients with lumbar spinal disorders, there is no consistent pattern across studies of opioids being associated with subsequent outcomes once potential confounders are accounted for, and therefore it is unlikely that there is a causal effect of opioid use on downstream outcomes. More specifically, among patients with LSS, the presence of treatment with opioids by itself should not be taken as an indicator that these patients are less likely to have improvements after epidural injections as compared to those not treated with opioids.

There were some limitations to the current study. First, data on treatment with opioids at baseline ascertained by patient report as part of the health utilization records was not available for all LESS trial participants, so we relied on EMR data regarding *filled* opioid prescriptions (which patients obtained but may not have actually taken) in 55% of the sample. Self-reported opioid use may be affected by factors such as recall bias and social stigma. Both self-report and filled prescription measures have limitations and may not

be perfectly associated with actual use. Both measures, however, are an improvement on measures of prescriptions written²⁶, which may or may not be filled. We adjusted for EMR vs. health utilization record ascertainment of baseline treatment with opioids in all multivariate analyses to minimize confounding by the method of ascertainment. Second, given that our study was conducted prior to the widespread availability of prescription drug monitoring programs, it is possible that the EMR-ascertained prevalence of baseline treatment of opioids in the current study was underestimated. On the other hand, given that the three study sites that provided EMR data on opioid treatment in the current study were chosen specifically because they were integrated health systems, it was likely less prevalent in these health systems than elsewhere at that time. Third, a relatively small percentage of the LESS trial participants were treated with opioids at randomization (21%) and these patients generally were not on high doses (average daily MED of 25.5 mg). This may have reduced our power to detect associations between baseline treatment with opioids and subsequent outcomes. However, given epidemiologic trends of decreases in opioid use which have occurred since 2014, power to detect associations with subsequent outcomes in patients with LSS would have been even more limited had this study been conducted at the current time.

Conclusions:

Among older adults with lumbar spinal stenosis receiving epidural injections in a randomized trial, baseline treatment with opioids was not associated with worse outcomes in terms of pain, functional limitations, or treatment crossover, after adjusting for confounding variables. These findings suggest that baseline treatment with opioids by itself should not be taken as an indicator that these patients are less likely to respond to epidural injections as compared to those not treated with opioids.

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References

1. Suri P, Rainville J, Kalichman L, Katz JN. Does this older adult with lower extremity pain have the clinical syndrome of lumbar spinal stenosis? *JAMA*. 2010;304(23):2628–2636. [PubMed: 21156951]
2. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*. 2010;303(13):1259–1265. [PubMed: 20371784]
3. Adogwa O, Davison MA, Vuong VD, et al. Long-Term Costs of Maximum Nonoperative Treatments in Patients With Symptomatic Lumbar Stenosis or Spondylolisthesis that Ultimately Required Surgery: A 5-Year Cost Analysis. *Spine*. 2019;44(6):424–430. [PubMed: 30130337]

4. Krebs EE, Gravely A, Nugent S, et al. Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial. *JAMA*. 2018;319(9):872–882. [PubMed: 29509867]
5. Deyo RA, Von Korff M, Durrkoop D. Opioids for low back pain. *BMJ (Clinical research ed)*. 2015;350:g6380.
6. Ashworth J, Green DJ, Dunn KM, Jordan KP. Opioid use among low back pain patients in primary care: Is opioid prescription associated with disability at 6-month follow-up? *Pain*. 2013;154(7):1038–1044. [PubMed: 23688575]
7. Webster BS, Verma SK, Gatchel RJ. Relationship between early opioid prescribing for acute occupational low back pain and disability duration, medical costs, subsequent surgery and late opioid use. *Spine*. 2007;32(19):2127–2132. [PubMed: 17762815]
8. Friedly JL, Bresnahan BW, Comstock B, et al. Study protocol- Lumbar Epidural steroid injections for Spinal Stenosis (LESS): a double-blind randomized controlled trial of epidural steroid injections for lumbar spinal stenosis among older adults. *BMC Musculoskelet Disord*. 2012;13:48. [PubMed: 22458343]
9. Friedly JL, Comstock BA, Turner JA, et al. A randomized trial of epidural glucocorticoid injections for spinal stenosis. *N Engl J Med*. 2014;371(1):11–21. [PubMed: 24988555]
10. Franklin GM, Stover BD, Turner JA, Fulton-Kehoe D, Wickizer TM, Disability Risk Identification Study C. Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort. *Spine*. 2008;33(2):199–204. [PubMed: 18197107]
11. Steenstra IA, Busse JW, Tolusso D, et al. Predicting time on prolonged benefits for injured workers with acute back pain. *J Occup Rehabil*. 2015;25(2):267–278. [PubMed: 25164779]
12. Morasco BJ, Yarborough BJ, Smith NX, et al. Higher Prescription Opioid Dose is Associated With Worse Patient-Reported Pain Outcomes and More Health Care Utilization. *J Pain*. 2017;18(4):437–445. [PubMed: 27993558]
13. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine*. 1983;8(2):141–144. [PubMed: 6222486]
14. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain*. 2001;94(2):149–158. [PubMed: 11690728]
15. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 2003;41(11):1284–1292. [PubMed: 14583691]
16. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med*. 2006;166(10):1092–1097. [PubMed: 16717171]
17. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain*. 1993;52(2):157–168. [PubMed: 8455963]
18. Osman A, Barrios FX, Gutierrez PM, Kopper BA, Merrifield T, Grittmann L. The Pain Catastrophizing Scale: further psychometric evaluation with adult samples. *J Behav Med*. 2000;23(4):351–365. [PubMed: 10984864]
19. Brazier J, Jones N, Kind P. Testing the validity of the Euroqol and comparing it with the SF-36 health survey questionnaire. *Qual Life Res*. 1993;2(3):169–180. [PubMed: 8401453]
20. Sharifzadeh Y, Kao MC, Sturgeon JA, Rico TJ, Mackey S, Darnall BD. Pain Catastrophizing Moderates Relationships between Pain Intensity and Opioid Prescription: Nonlinear Sex Differences Revealed Using a Learning Health System. *Anesthesiology*. 2017;127(1):136–146. [PubMed: 28614083]
21. Scherrer JF, Ahmedani B, Autio K, et al. The Prescription Opioids and Depression Pathways Cohort Study. *J Psychiatr Brain Sci*. 2020;5.
22. Trevino CM, deRoon-Cassini T, Brasel K. Does opiate use in traumatically injured individuals worsen pain and psychological outcomes? *J Pain*. 2013;14(4):424–430. [PubMed: 23548492]
23. Hoffman EM, Watson JC, St Sauver J, Staff NP, Klein CJ. Association of Long-term Opioid Therapy With Functional Status, Adverse Outcomes, and Mortality Among Patients With Polyneuropathy. *JAMA Neurol*. 2017;74(7):773–779. [PubMed: 28531306]

24. Gold LS, Hansen RN, Avins AL, et al. Associations of Early Opioid Use With Patient-reported Outcomes and Health Care Utilization Among Older Adults With Low Back Pain. *Clin J Pain.* 2018;34(4):297–305. [PubMed: 28915153]
25. Sullivan MD, Edlund MJ, Zhang L, Unutzer J, Wells KB. Association between mental health disorders, problem drug use, and regular prescription opioid use. *Arch Intern Med.* 2006;166(19):2087–2093. [PubMed: 17060538]
26. Fischer MA, Stedman MR, Lii J, et al. Primary medication non-adherence: analysis of 195,930 electronic prescriptions. *J Gen Intern Med.* 2010;25(4):284–290. [PubMed: 20131023]

Key Points:

1. Among older adults with lumbar spinal stenosis who are receiving epidural injections, patients treated with opioids at baseline did not differ significantly from those not treated with opioids in improvement at 3 and 6 weeks in back pain intensity, leg pain intensity, or RMDQ scores.
2. Among older adults with lumbar spinal stenosis who are receiving epidural injections, no statistically significant difference was observed in rates of cross-over to the epidural injection treatment not originally received between patients who were treated with opioids at baseline and those who were not.
3. Patients treated with opioids at baseline had lower quality of life and greater levels of depression, anxiety, and catastrophizing.

Table 1:

Demographic and clinical characteristics by baseline treatment with opioids among older adults with lumbar spinal stenosis receiving epidural steroid injections with or without steroids. **Bolded variables indicate p<0.05.**

n (%) or Mean (Interquartile range)	Lidocaine-Alone		Glucocorticoid-Lidocaine	
	Opioid Treatment at Baseline (N=37)	No Opioid Treatment at Baseline (N=143)	Opioid Treatment at Baseline (N=40)	No Opioid Treatment at Baseline (N=151)
Age	66.6 (59.0, 74.0)	68.8 (60.0, 76.0)	66.8 (58.0, 75.3)	67.9 (59.0, 75.0)
Female	19 (51)	74 (52)	23 (58)	90 (60)
Hispanic	1 (3)	4 (3)	2 (5)	9 (6)
Non-White Race	17 (46)	40 (28)	14 (35)	47 (31)
White Race	20 (54)	103 (72)	26 (65)	104 (69)
Married/living with partner	17 (46)	81 (57)	21 (53)	98 (65)
Employment status				
<i>Full/part time</i>	13 (35)	50 (35)	10 (25)	43 (28)
<i>Retired, not disabled</i>	16 (43)	65 (45)	16 (40)	73 (48)
<i>Retired, disabled</i>	5 (14)	15 (10)	11 (28)	19 (13)
<i>Other</i>	3 (8)	13 (9)	3 (8)	16 (11)
Education				
<i>High school equivalent or less</i>	16 (43)	44 (31)	14 (35)	43 (28)
<i>Some college, vocational/tech</i>	13 (35)	36 (25)	16 (40)	54 (36)
<i>College degree or more</i>	8 (22)	63 (44)	10 (25)	54 (36)
Duration of pain				
<i><3 months</i>	8 (22)	30 (21)	6 (15)	16 (11)
<i>3 to <12 months</i>	8 (22)	46 (32)	17 (43)	39 (26)
<i>1 to 5 years</i>	10 (27)	27 (19)	7 (18)	59 (39)
<i>>5 years</i>	11 (30)	40 (28)	10 (25)	37 (25)
Expectation of pain relief ¹	7.4 (6, 9)	7.8 (6, 10)	7.8 (7, 9)	7.6 (6–9)
Roland Morris Disability Questionnaire				
<i>Baseline</i>	16.3 (15, 19.5)	15.3 (12, 19)	17.3 (14, 21)	15.8 (12, 19)
<i>6 weeks</i>	13.1 (7.5, 19)	12.0 (7, 17)	12.5 (7, 18)	11.7 (8, 17)
<i>Change baseline to 6 weeks</i> ²	-3.2 (-6.5, 1)	-3.3 (-6, 0)	-4.8 (-8, -1)	-4.1 (-7, 0)
Back Pain intensity				
<i>Baseline</i>	7.6 (6.5, 9)	6.4 (5, 8)	6.5 (5, 9)	6.8 (5, 9)
<i>6 weeks</i>	4.2 (2, 6)	4.3 (2, 6)	4.6 (2, 7)	4.2 (2, 7)
<i>Change baseline to 6 weeks</i>	-3.4 (-6, -1)	-2.1 (-4, 0)	-2.0 (-4, 0)	-2.6 (-5, 0)
Leg Pain intensity				
<i>Baseline</i>	7.6 (6.5, 8.5)	7.1 (6, 8)	7.3 (6, 8)	7.3 (6, 9)
<i>6 weeks</i>	4.5 (1.5, 7)	4.4 (2, 7)	4.2 (1, 7)	4.5 (2, 7)
<i>Change baseline to 6 weeks</i>	-3.1 (-5, 0)	-2.7 (-5, 0)	-3.1 (-5, 0)	-2.8 (-5, -1)

n (%) or Mean (Interquartile range)	Lidocaine-Alone		Glucocorticoid-Lidocaine	
	Opioid Treatment at Baseline (N=37)	No Opioid Treatment at Baseline (N=143)	Opioid Treatment at Baseline (N=40)	No Opioid Treatment at Baseline (N=151)
Depression (PHQ-8) ³				
<i>Baseline</i>	7.2 (3, 9.5)	5.1 (2, 7)	9.4 (5, 14)	6.5 (2, 9)
<i>6 weeks</i>	5.5 (1, 7.5)	4.2 (1, 6)	4.9 (2, 7)	4.3 (1, 7)
<i>Change baseline to 6 weeks</i>	-1.7 (-4, 1)	-1.0 (-3, 1)	-4.5 (-9, -1)	-2.2 (-4, 1)
Anxiety (GAD-7) ⁴				
<i>Baseline</i>	5.9 (2.5, 6.5)	3.9 (0, 6)	5.6 (2, 8)	4.1 (1, 6)
<i>6 weeks</i>	3.7 (0, 7)	3.1 (0, 5)	3.8 (0, 6)	3.1 (0, 5)
<i>Change baseline to 6 weeks</i>	-2.3 (-4.5, 0)	-0.8 (-3, 1)	-1.8 (-4, 0)	-1.1 (-3, 0)
Fear Avoidance Beliefs Questionnaire				
<i>Baseline</i>	19.3 (15, 26)	18.9 (14, 26)	21.1 (17.5, 26)	19.2 (13, 26)
Pain Catastrophizing Scale				
<i>Baseline</i>	21.4 (12, 31)	17.1 (8, 23)	21.8 (13, 30)	18.0 (9, 25)
Self-Rated Health (EQ-5D-VAS)				
<i>Baseline</i>	65.2 (50, 80)	68.3 (59, 80)	61.6 (50, 80)	67.6 (50, 85)
<i>6 weeks</i>	67.9 (60, 83)	71.3 (60, 80)	68.1 (60, 80)	66.2 (50, 80)
<i>Change baseline to 6 week</i> ⁶	2.7 (-10, 15)	3.0 (-5, 15)	6.5 (-10, 20)	-1.3 (-10, 10)

¹ **Pain Expectation Scale:** A numeric rating scale that asks patients to rate their expected pain in 3 months based on a 0–10 scale with 0= no pain and 10= worst pain imaginable.

² Negative values for change in Roland Morris Disability Questionnaire (RMDQ), back and leg pain numeric rating scales, PHQ-8, and GAD-7 scores indicate improvements.

³ PHQ-8: Patient Health Questionnaire depression 8-item scale

⁴ GAD-7: Generalized Anxiety Disorder 7-item scale

⁵ EQ-5D-VAS: EuroQOL visual analogue scale

⁶ Negative values for change in EQ-5D-VAS indicates worse outcomes.

Table 2:Changes in patient-reported pain and function associated with baseline opioid treatment, crude and adjusted.¹

Variable	N ²	Crude Mean (95% CI) ³		Adjusted Mean (95% CI) ³		Adjusted Difference in Means (95% CI) ⁴
		Opioid Treatment at Baseline	No Opioid Treatment at Baseline	Opioid Treatment at Baseline	No Opioid Treatment at Baseline	
Back Pain Numeric Rating Scale						
<i>Change from baseline to:</i>						
3 weeks	358	-2.5 (-3.2, -1.8)	-2.5 (-2.8, -2.1)	-2.4 (-3.0, -1.9)	-2.5 (-2.8, -2.2)	0.1 (-0.6, 0.7)
6 weeks	359	-2.6 (-3.3, -1.9)	-2.4 (-2.7, -2.0)	-2.6 (-3.2, -2.0)	-2.4 (-2.7, -2.1)	-0.2 (-0.8, 0.5)
6 months	336	-1.6 (-2.3, -0.9)	-2.6 (-3.0, -2.3)	-1.6 (-2.2, -1.1)	-2.7 (-3.0, -2.4)	1.1 (0.4, 1.7)
12 months	328	-2.2 (-2.9, -1.4)	-2.5 (-2.9, -2.1)	-2.3 (-2.9, -1.6)	-2.6 (-2.9, -2.3)	0.3 (-0.4, 1.0)
Leg Pain Numeric Rating Scale						
<i>Change from baseline to:</i>						
3 weeks	358	-2.8 (-3.4, -2.2)	-2.6 (-3.0, -2.3)	-2.9 (-3.4, -2.3)	-2.6 (-2.9, -2.3)	-0.2 (-0.9, 0.4)
6 weeks	359	-3.1 (-3.8, -2.4)	-2.7 (-3.1, -2.4)	-3.2 (-3.8, -2.6)	-2.8 (-3.1, -2.4)	-0.4 (-1.1, 0.3)
6 months	336	-2.1 (-2.8, -1.4)	-2.9 (-3.3, -2.6)	-2.2 (-2.8, -1.6)	-3.0 (-3.3, -2.7)	0.8 (0.1, 1.5)
12 months	329	-2.2 (-2.9, -1.4)	-2.9 (-3.2, -2.5)	-2.4 (-3.1, -1.7)	-3.0 (-3.3, -2.6)	0.6 (-0.2, 1.3)
Function (Roland Morris Disability Questionnaire)						
<i>Change from baseline to:</i>						
3 weeks	359	-4.4 (-5.5, -3.2)	-3.4 (-4.1, -2.8)	-4.3 (-5.4, -3.2)	-3.5 (-4.1, -2.9)	-0.8 (-2.1, 0.4)
6 weeks	356	-4.0 (-5.3, -2.8)	-3.7 (-4.4, -3.1)	-3.9 (-5.1, -2.7)	-3.8 (-4.4, -3.2)	-0.1 (-1.5, 1.3)
6 months	334	-4.0 (-5.3, -2.7)	-3.9 (-4.5, -3.2)	-4.0 (-5.2, -2.8)	-4.2 (-4.8, -3.6)	0.2 (-1.2, 1.6)
12 months	329	-3.9 (-5.4, -2.5)	-4.0 (-4.8, -3.3)	-4.3 (-5.7, -2.9)	-4.3 (-5.0, -3.6)	0 (-1.5, 1.6)

Statistically significant between-group differences at a specific time point are indicated in **bold**

¹ Adjusted for whether patient had EMR/health utilization record baseline opioid treatment data, whether the patient was randomized to receive glucocorticoid-lidocaine/lidocaine-alone, age, gender, race (white vs not white), partner, employment (full/part time vs. other), education, duration of pain, expectations of pain relief, and baseline RMDQ, back pain NRS, leg pain NRS, PHQ-8, GAD-7, FABQ, PCS, and EQ-5D-VAS.

² Only patients with data for the outcome and adjustment variables are included in both the crude and adjusted estimates so they are comparable.

³ Negative values indicate an improvement in back and leg pain NRS and an improvement in RMDQ score.

⁴ Negative values indicate a relative improvement in pain or disability in those treated with opioids at baseline compared to those not treated with opioids at baseline.